US009480578B2

(12) **United States Patent**
Pinto

(10) **Patent No.: US 9,480,578 B2**
(45) **Date of Patent: *Nov. 1, 2016**

(54) **EXPANDABLE INTERBODY FUSION DEVICE WITH GRAFT CHAMBERS**

(71) Applicant: **SPINE WAVE, INC.**, Shelton, CT (US)

(72) Inventor: **Fabio Amaral Pinto**, Stamford, CT (US)

(73) Assignee: **SPINE WAVE, INC**, Shelton, CT (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 274 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/265,482**

(22) Filed: **Apr. 30, 2014**

(65) **Prior Publication Data**

US 2014/0236298 A1 Aug. 21, 2014

Related U.S. Application Data

(63) Continuation of application No. 13/689,046, filed on Nov. 29, 2012, now Pat. No. 8,715,351.

(51) **Int. Cl.**

A61F 2/44	(2006.01)
A61F 2/28	(2006.01)
A61F 2/30	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/447*** (2013.01); *A61F 2002/2835* (2013.01); *A61F 2002/305* (2013.01); *A61F 2002/30331* (2013.01); *A61F 2002/30556* (2013.01); *A61F 2002/30599* (2013.01); *A61F 2002/30601* (2013.01); *A61F 2002/30878* (2013.01); *A61F 2002/30904* (2013.01)

(58) **Field of Classification Search**

USPC 623/17.13, 17.15, 17.16

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,486,505 A	12/1969	Morrison
4,524,766 A	6/1985	Petersen
4,683,476 A	7/1987	Ferrari et al.
4,736,738 A	4/1988	Lipovsek et al.
4,755,797 A	7/1988	Kanaya
4,863,476 A	9/1989	Shepperd
4,888,024 A	12/1989	Powlan
5,059,193 A	10/1991	Kuslich
5,192,326 A	3/1993	Bao et al.
5,192,327 A	3/1993	Brantigan

(Continued)

FOREIGN PATENT DOCUMENTS

FR	2639823 A1	6/1990
FR	2719763 A1	11/1995

OTHER PUBLICATIONS

PCT Search Report for corresponding PCT Application No. PCT/US2008/064534.

(Continued)

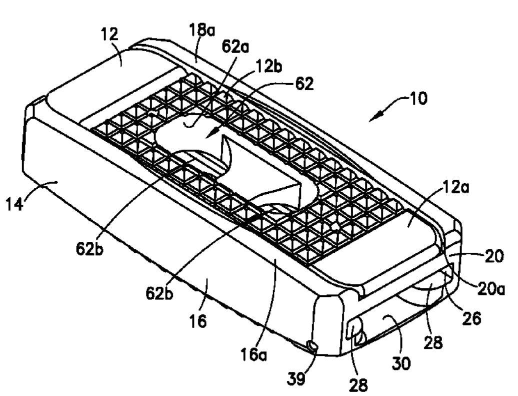
Primary Examiner — Samuel Hanna

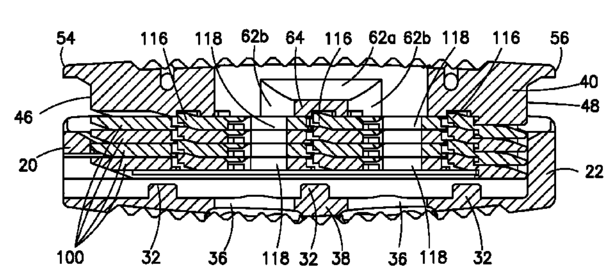
(74) *Attorney, Agent, or Firm* — Hoffman & Baron, LLP

(57) **ABSTRACT**

An expandable interbody fusion device includes superior and inferior plates that are configured to receive a sequentially inserted stack of expansion members or wafers in interlocking engagement. The superior and inferior plates have openings therethrough in communication with aligned holes through the wafers for receipt and containment of bone graft to promote fusion between opposing vertebral bodies. One of said superior and inferior endplates has a multi-contoured opening extending therethrough.

14 Claims, 8 Drawing Sheets





(56) **References Cited**

U.S. PATENT DOCUMENTS

5,197,971 A	3/1993	Bonutti	
5,298,254 A	3/1994	Prewett et al.	
5,431,658 A	7/1995	Moskovich	
5,439,684 A	8/1995	Prewett et al.	
5,505,732 A	4/1996	Michelson	
5,514,180 A	5/1996	Heggeness et al.	
5,522,899 A	6/1996	Michelson	
5,571,109 A	11/1996	Bertagnoli	
5,591,235 A	1/1997	Kuslich	
5,609,636 A	3/1997	Kohrs et al.	
5,645,599 A	7/1997	Samani	
5,702,454 A	12/1997	Baumgartner	
5,755,797 A	5/1998	Baumgartner	
5,756,127 A	5/1998	Grisoni et al.	
5,766,252 A	6/1998	Henry et al.	
5,836,948 A	11/1998	Zucherman et al.	
5,860,977 A	1/1999	Zucherman et al.	
5,891,147 A	4/1999	Moskovitz et al.	
5,951,553 A	9/1999	Betz et al.	
5,980,522 A	11/1999	Koros et al.	
6,033,411 A	3/2000	Preissman	
6,045,579 A	4/2000	Hochshuler et al.	
6,066,154 A	5/2000	Reiley et al.	
6,074,390 A	6/2000	Zucherman et al.	
6,110,179 A	8/2000	Flivik et al.	
6,110,210 A	8/2000	Norton et al.	
6,159,211 A	12/2000	Boriani et al.	
6,159,244 A	12/2000	Suddaby	
6,190,414 B1	2/2001	Young et al.	
6,200,347 B1	3/2001	Anderson et al.	
6,241,771 B1	6/2001	Gresser et al.	
6,273,916 B1	8/2001	Murphy	
6,279,916 B1	8/2001	Stecher	
6,287,308 B1	9/2001	Betz et al.	
6,287,309 B1	9/2001	Baccelli et al.	
6,290,724 B1	9/2001	Marino	
6,387,130 B1	5/2002	Stone et al.	
6,395,034 B1	5/2002	Suddaby	
6,402,750 B1	6/2002	Atkinson et al.	
6,419,705 B1	7/2002	Erickson	
6,432,107 B1	8/2002	Ferree	
6,436,142 B1	8/2002	Paes et al.	
6,478,800 B1	11/2002	Fraser et al.	
6,488,710 B2	12/2002	Besselink	
6,500,205 B1	12/2002	Michelson	
6,520,993 B2	2/2003	James et al.	
6,562,074 B2	5/2003	Gerbec et al.	
6,595,998 B2	7/2003	Johnson et al.	
6,620,196 B1	9/2003	Trieu	
6,648,917 B2	11/2003	Gerbec et al.	
6,656,178 B1	12/2003	Veldhuizen et al.	
6,666,888 B1 *	12/2003	Jackson	A61F 2/446 623/17.11
6,726,691 B2	4/2004	Osorio et al.	
6,740,093 B2	5/2004	Hochschuler et al.	
6,837,904 B2	1/2005	Ralph et al.	
6,852,095 B1	2/2005	Ray	
6,852,126 B2	2/2005	Ahlgren	
6,852,129 B2	2/2005	Gerbec et al.	
6,863,673 B2	3/2005	Gerbec et al.	
6,908,485 B2	6/2005	Crozet et al.	
6,997,929 B2	2/2006	Manzi et al.	
7,044,972 B2	5/2006	Mathys, Jr. et al.	
7,094,257 B2	8/2006	Mujwid et al.	
7,118,580 B1	10/2006	Beyersdorff et al.	
7,591,852 B2	9/2009	Prosser	
7,931,688 B2	4/2011	Landry et al.	
7,967,867 B2	6/2011	Barreiro et al.	
8,182,537 B2	5/2012	Refai et al.	
8,308,805 B2	11/2012	Lynn et al.	
8,574,300 B2 *	11/2013	McManus et al.	A61F 2/44 623/17.11
2002/0026195 A1	2/2002	Layne et al.	
2002/0147497 A1	10/2002	Belef et al.	
2002/0177897 A1	11/2002	Michelson	
2003/0171812 A1	9/2003	Grunberg et al.	
2004/0019354 A1	1/2004	Johnson et al.	
2004/0064144 A1	4/2004	Johnson et al.	
2004/0220580 A1	11/2004	Johnson et al.	
2005/0027364 A1	2/2005	Kim et al.	
2005/0149194 A1	7/2005	Ahlgren	
2006/0058807 A1	3/2006	Landry et al.	
2006/0058880 A1	3/2006	Wysocki et al.	
2006/0129244 A1	6/2006	Ensign	
2008/0161924 A1	7/2008	Viker	
2008/0172127 A1	7/2008	Perez-Cruet et al.	
2008/0300598 A1 *	12/2008	Barreiro	A61F 2/4611 606/63
2009/0118836 A1	5/2009	Cordaro	
2009/0198339 A1	8/2009	Kleiner et al.	
2009/0222100 A1	9/2009	Cipoletti et al.	
2010/0179656 A1	7/2010	Theofilos	
2010/0286779 A1	11/2010	Thibodeau	
2010/0292796 A1	11/2010	Greenhalgh et al.	
2011/0130835 A1	6/2011	Ashley et al.	
2012/0158144 A1	6/2012	Ullrich, Jr. et al.	
2013/0211526 A1 *	8/2013	Alheidt	A61F 2/4611 623/17.16

OTHER PUBLICATIONS

Baddeley, S. and Cullen, J.C., "The Use of Methylmethacrylate in the Treatment of Giant Cell Tumours of the Proximal Tibia", Aust. N.Z. J. Surg. vol. 49—No. 1, Feb. 1979, 3 pp.
Campanacci, M., Gui, L., Ranieri, L., Savini, R., "Treatment of Tibial Plateau Fractures", Chi. Org. Mov. 72(3), Dec. 1975 (Italian text), pp. 234-256, English Translation, 15 pp.
Kyphon Inc., Surgical Technique Manual Nov. 16, 1999, pp. 5, 6, 9, 16-19.
Kyphon Vertebral Treatment Notebook, date unknown, 9 pp.
Kyphon web page, www.kyphon.com, Mar. 13, 2001, 1 p.
AOM Technique Manual, "Controlled Delivery for Osteoplasty, A Vertebroplasty Application", Cat #900.001—Rev B—date unknown.
Medtronic SOFAMOR DANEK, "VERTE-STACK™, PEEK Stackable Corpectomy Device, Surgical Technique", date unknown, 8 pp.
Signus Medical, TETRIS, Sep. 2003, 1 p.
Blackstone Medical Inc., Construx™ PEEK VBR System, 2005, www.blackstonemedical.com, 1 p.
Globus Medical, SUSTAIN™ R SMALL, date unknown, 6 pp.

* cited by examiner

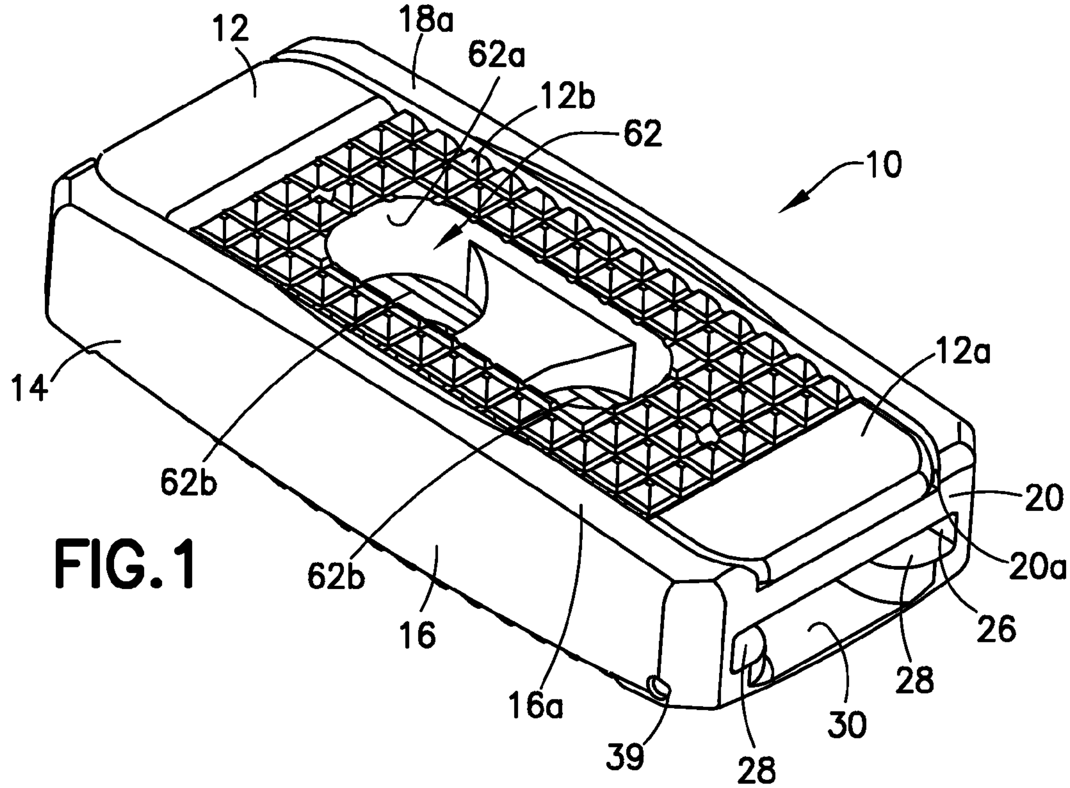

12
18a
62a
12b
62
10
14
12a
62b
20
20a
62b
26
16
28
16a
30
39
28

FIG.1

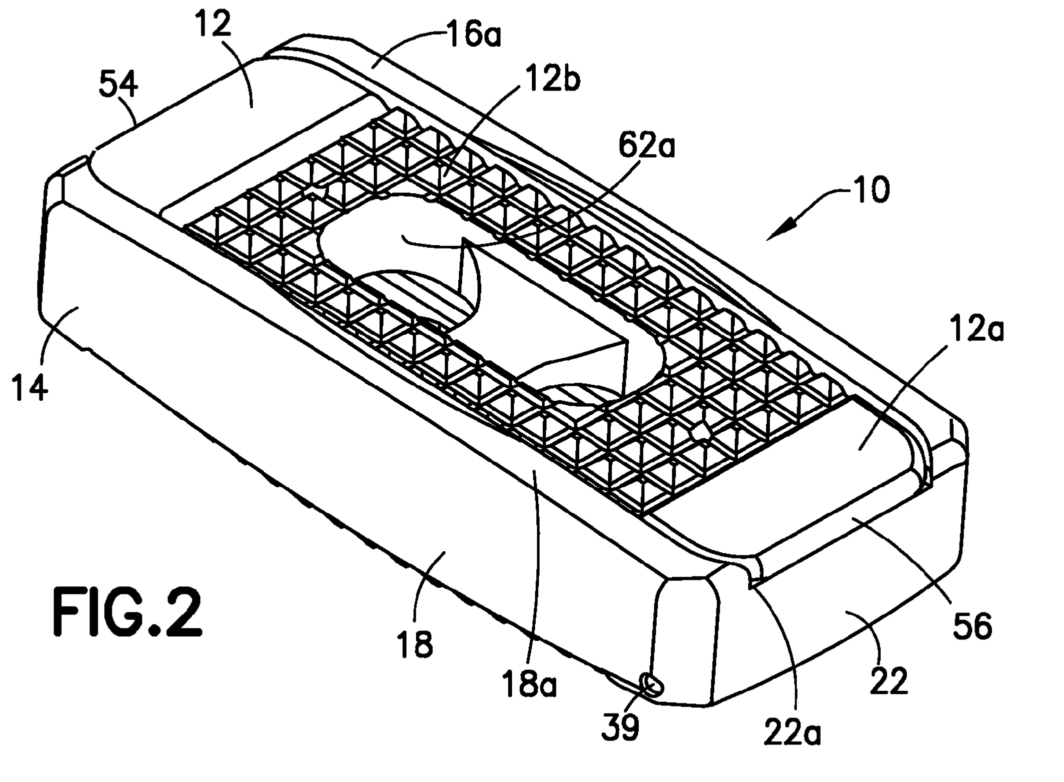

12
16a
54
12b
62a
10
14
12a
18
56
18a
22
39
22a

FIG.2

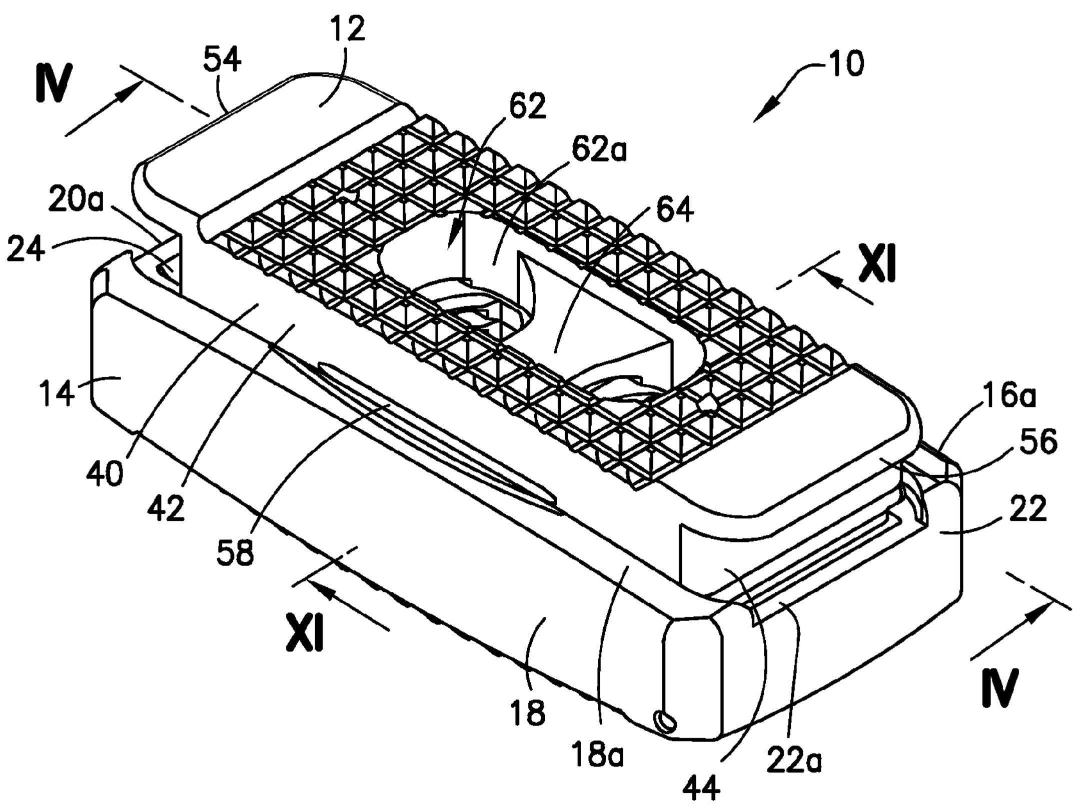

12
54
10
IV
62
62a
20a
64
24
XI
14
16a
56
40
42
22
58
XI
IV
18
18a
44
22a

FIG.3

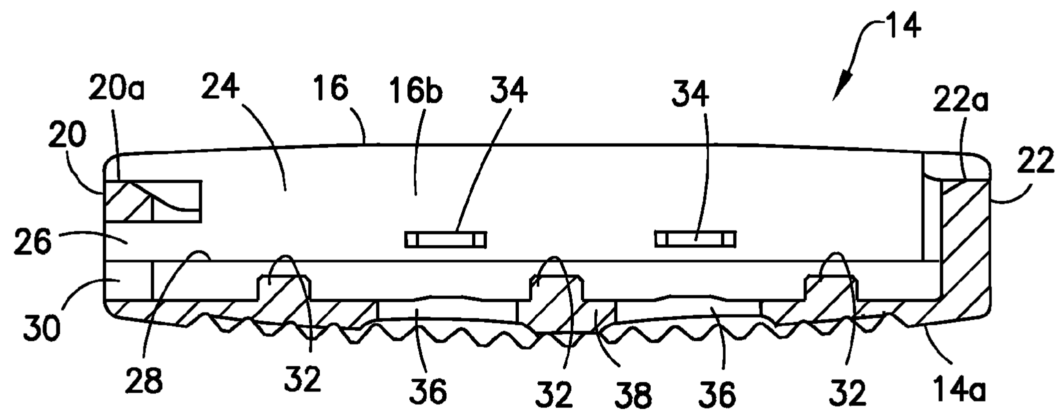

14
20a
24
16
16b
34
34
22a
20
22
26
30
28
32
36
32
38
36
32
14a

FIG.4

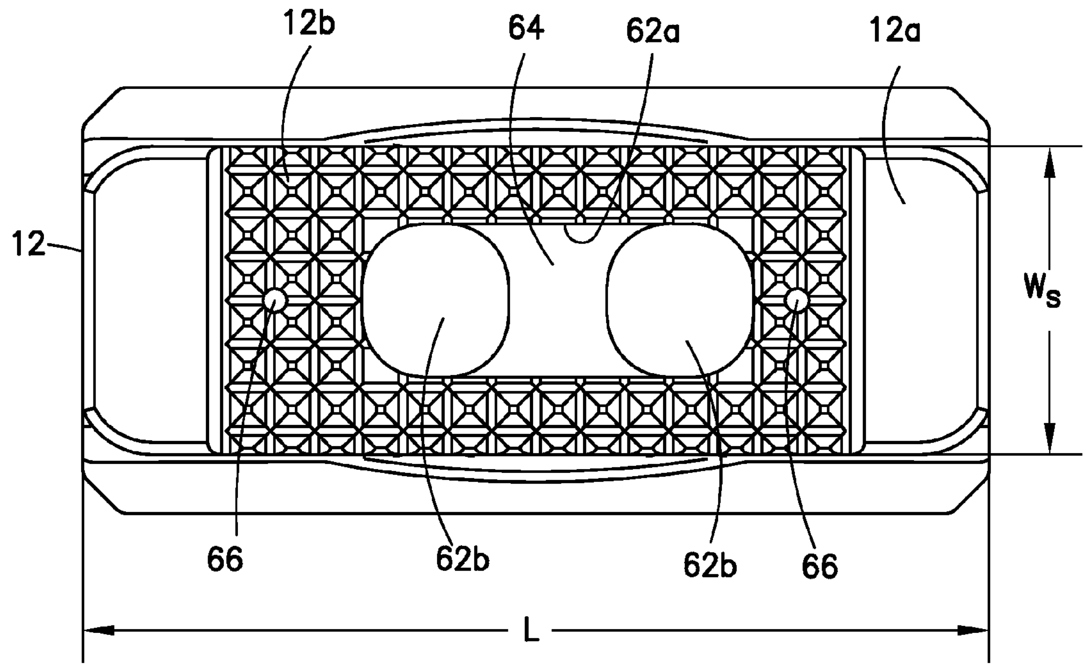


FIG.5

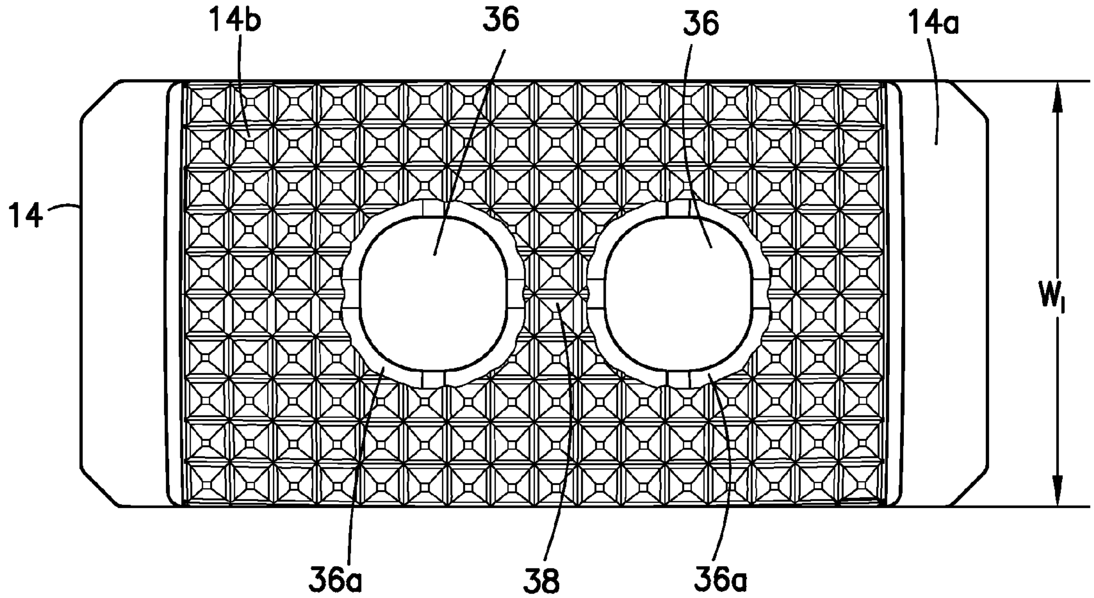


FIG.6

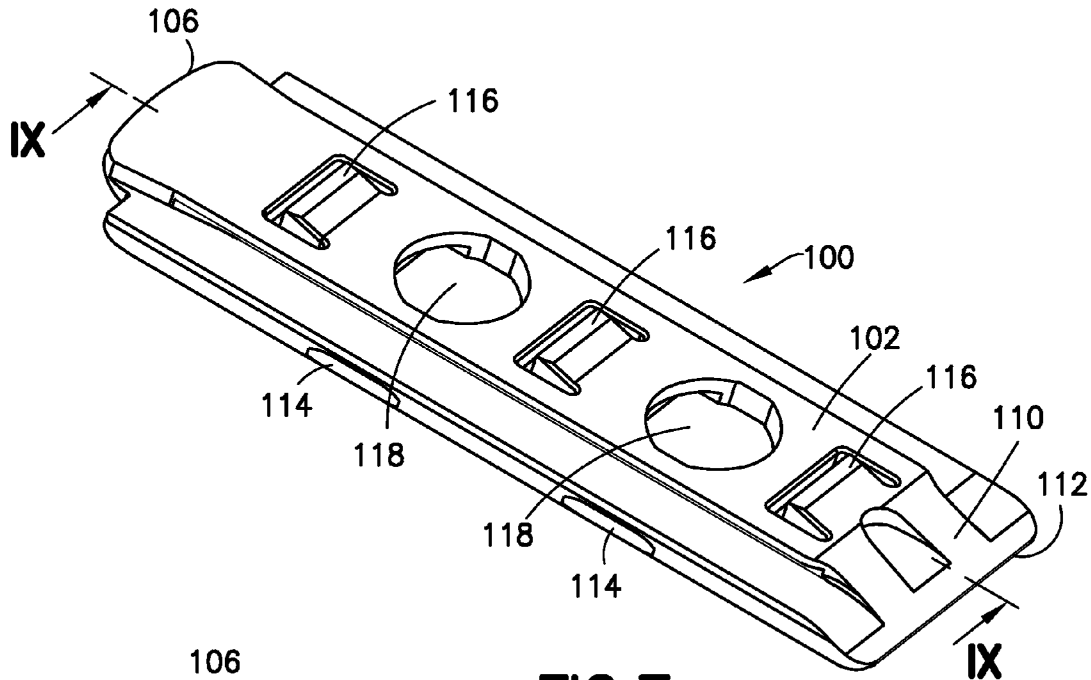

106
IX
116
116
100
102
116
110
112
114
118
118
114
IX

FIG.7

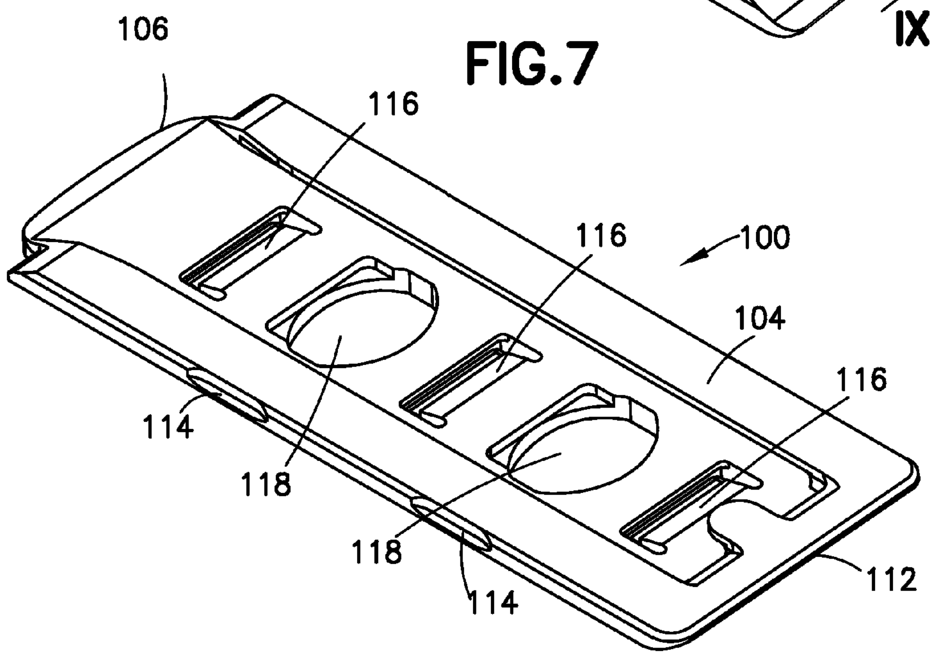

106
116
116
100
104
116
114
118
118
114
112

FIG.8

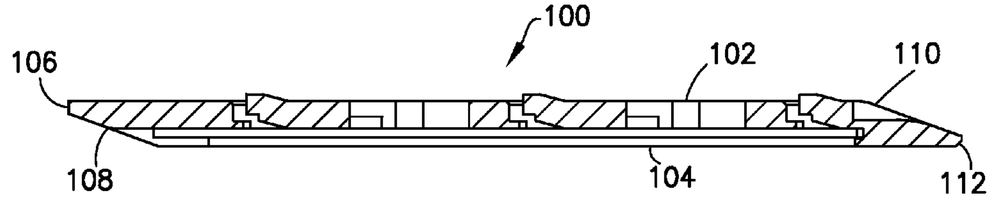


FIG.9

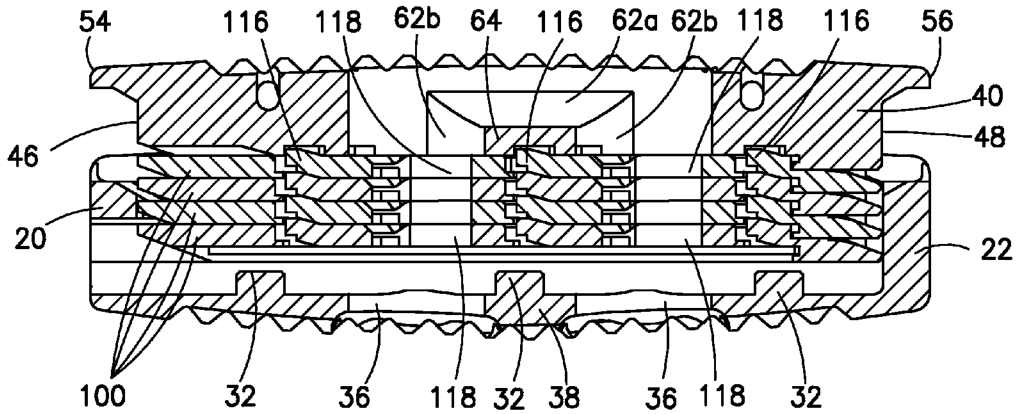


FIG.10

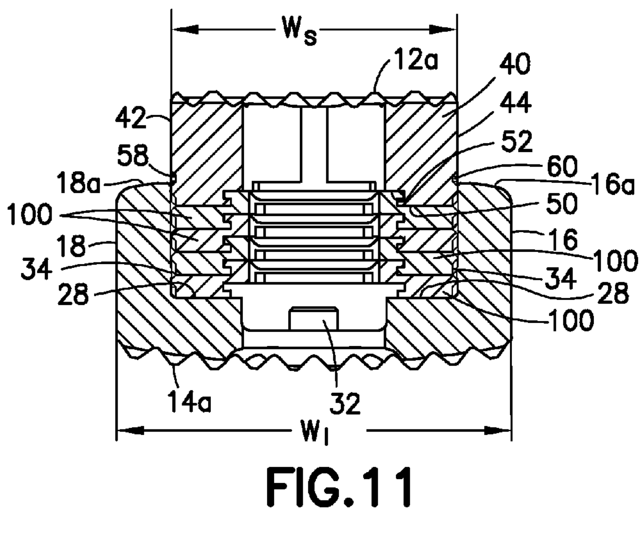


FIG.11

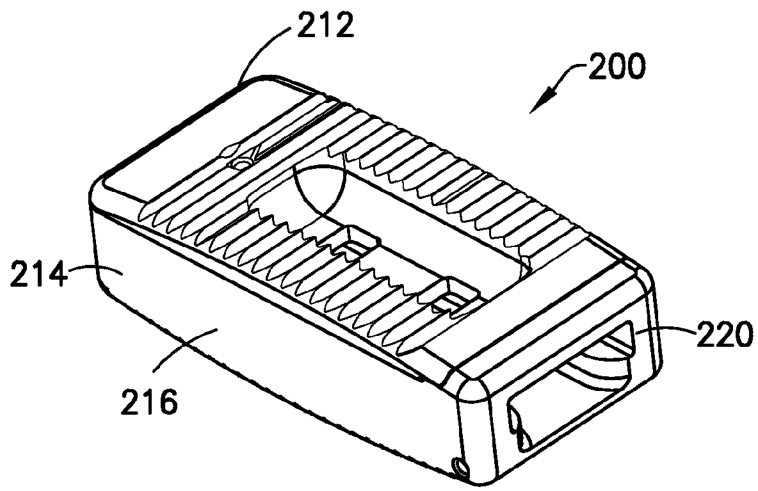


FIG.12

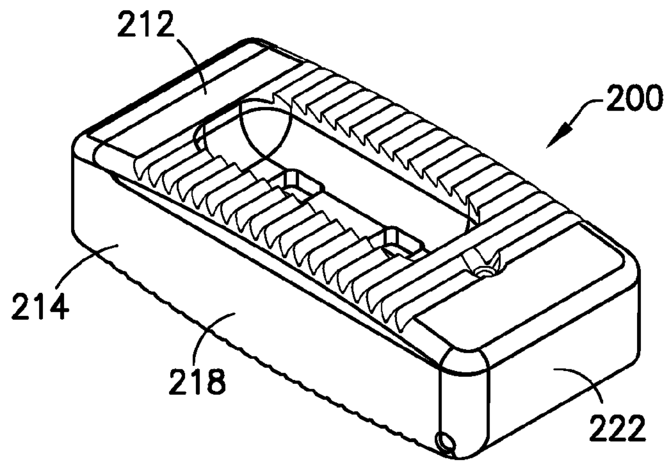


FIG.13

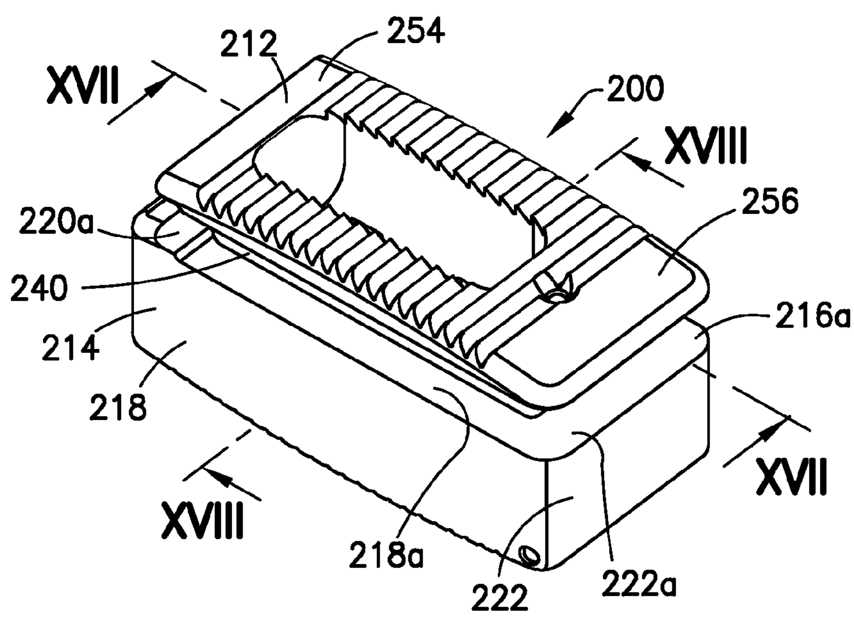


FIG.14

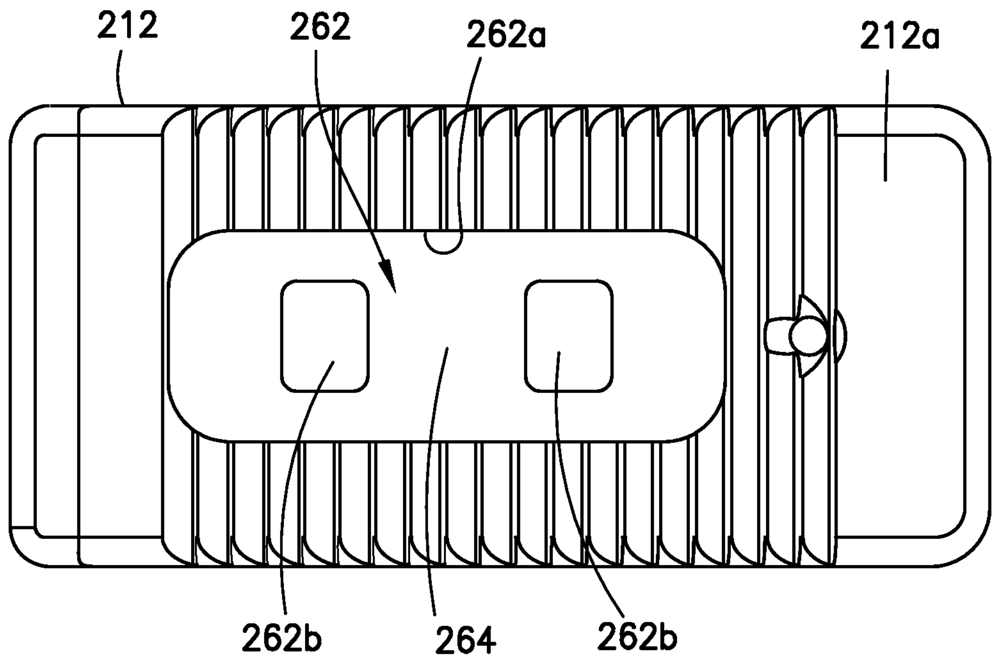

212
262
262a
212a
262b
264
262b

FIG.15

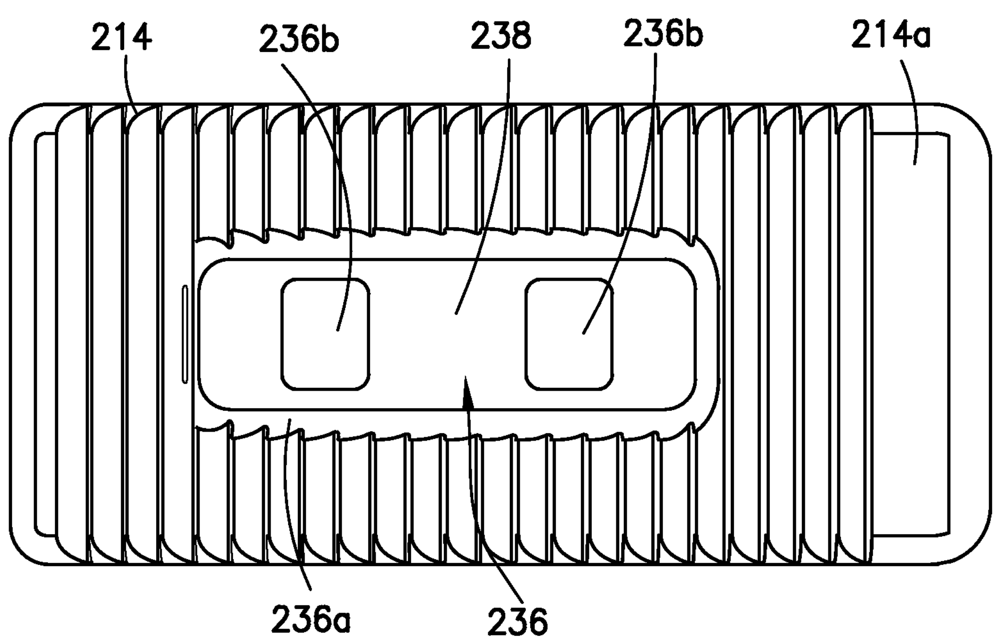

214
236b
238
236b
214a
236a
236

FIG.16

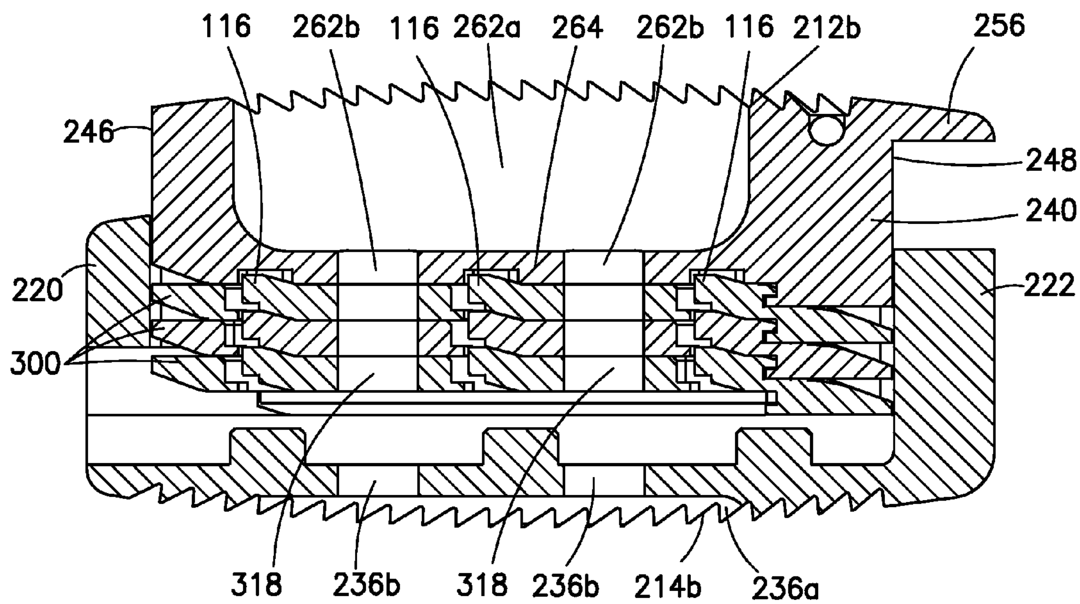

116
262b
116
262a
264
262b
116
212b
256
246
248
240
220
222
300
318
236b
318
236b
214b
236a

FIG.17

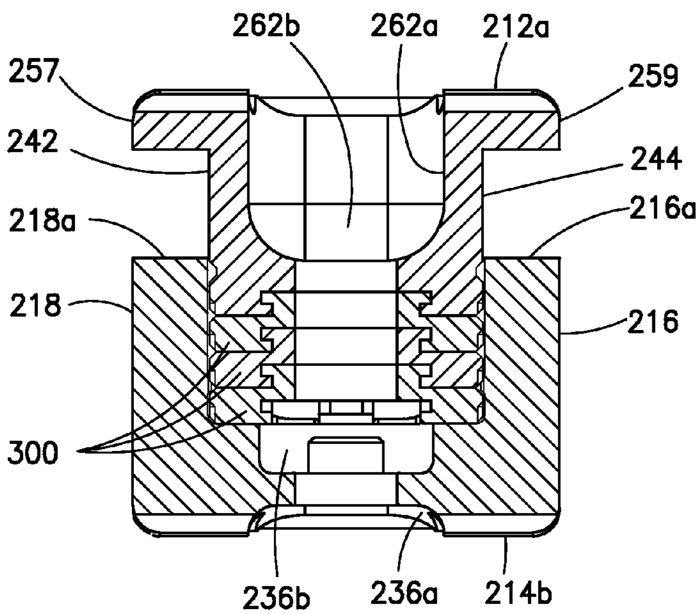

262b
262a
212a
257
259
242
244
218a
216a
218
216
300
236b
236a
214b

FIG.18

EXPANDABLE INTERBODY FUSION DEVICE WITH GRAFT CHAMBERS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 13/689,046, filed Nov. 29, 2012, now U.S. Pat. No. 8,715,351, the entire contents of which are incorporated by reference herein.

FIELD OF THE INVENTION

The subject invention relates generally to the field of spinal implants and more particularly to expandable interbody fusion devices with graft chambers.

BACKGROUND OF THE INVENTION

Spinal implants such as interbody fusion devices are used to treat degenerative disc disease and other damages or defects in the spinal disc between adjacent vertebrae. The disc may be herniated or suffering from a variety of degenerative conditions, such that the anatomical function of the spinal disc is disrupted. Most prevalent surgical treatment for these conditions is to fuse the two vertebrae surrounding the affected disc. In most cases, the entire disc will be removed, except for a portion of the annulus, by way of a discectomy procedure. A spinal fusion device is then introduced into the intradiscal space and suitable bone graft or bone substitute material is placed substantially in and/or adjacent the device in order to promote fusion between two adjacent vertebrae.

Certain spinal devices for achieving fusion are also expandable so as to correct disc height between the adjacent vertebrae. Examples of expandable interbody fusion devices are described in U.S. Pat. No. 6,595,998 entitled "Tissue Distraction Device", which issued on Jul. 22, 2003 (the '998 patent), U.S. Pat. No. 7,931,688 entitled "Expandable Interbody Fusion Device", which issued on Apr. 26, 2011 (the '688 patent), and U.S. Pat. No. 7,967,867 entitled "Expandable Interbody Fusion Device", which issued on Jun. 28, 2011 (the '867 patent). The '998 patent, the '688 patent and the '867 patent each discloses sequentially introducing in situ a series of elongate inserts referred to as wafers in a percutaneous approach to incrementally distract opposing vertebral bodies to stabilize the spine and correct spinal height, the wafers including features that allow adjacent wafers to interlock in multiple degrees of freedom. The '998 patent, the '688 patent and the '867 patent are assigned to the same assignee as the present invention, the disclosures of these patents being incorporated herein by reference in their entirety.

Certain interbody fusion devices also include hollow portions or chambers that are filled with suitable material such as bone graft to promote fusion between vertebral bodies. The extent and size of the chambers establish areas of contact that are configured so as to assure maximum contact between the bone graft and the vertebral bodies. Sufficient surface area of the device surrounding the chambers needs to be maintained in order to provide an appropriate load bearing surface to withstand the compressive forces exerted by the opposing vertebral bodies. In addition, where expandable interbody fusion devices are used to correct height within the intradiscal space, the effect of shear forces on the expanded device due to torsional movement of the spine also needs to be considered.

Accordingly, there is a need to develop expandable interbody fusion devices with bone graft chambers that take into account and balance these factors.

SUMMARY OF THE INVENTION

It is an object of the invention to provide an improved expandable device with openings serving as bone graft chambers for implantation into the intradiscal space between two opposing vertebral bodies of a spine.

DESCRIPTION OF THE FIGURES

FIGS. **1** and **2** are rear and front perspective views respectively of an expandable interbody fusion device in unexpanded condition in accordance with one embodiment of the present invention.

FIG. **3** is a front perspective view of the expandable interbody fusion device of FIG. **2** in expanded condition.

FIG. **4** is a cross section of the inferior endplate of the interbody fusion device as seen along the viewing lines IV-IV of FIG. **3**.

FIG. **5** is a top plan view of the interbody fusion device of FIG. **1**.

FIG. **6** is a bottom plan view of the interbody fusion device of FIG. **1**.

FIG. **7** is a top perspective view of an interlocking wafer serving as an expansion member to expand the interbody fusion device to the expanded condition shown in FIG. **3**.

FIG. **8** is a bottom perspective view of the interlocking wafer shown in FIG. **7**.

FIG. **9** is cross section of the interlocking wafer of FIG. **7** as seen along viewing lines IX-IX of FIG. **7**.

FIG. **10** is a cross section of the expanded interbody fusion device as seen along the viewing lines IV-IV of FIG. **3**.

FIG. **11** is a cross section of the expanded interbody fusion device as seen along the viewing lines XI-XI of FIG. **3**.

FIGS. **12** and **13** are rear and front perspective views respectively of an expandable interbody fusion device in unexpanded condition in accordance with another embodiment of the present invention.

FIG. **14** is a front perspective view of the expandable interbody fusion device of FIG. **13** in expanded condition.

FIG. **15** is a top plan view of the interbody fusion device of FIG. **12**.

FIG. **16** is a bottom plan view of the interbody fusion device of FIG. **12**.

FIG. **17** is a cross section of the expanded interbody fusion device as seen along the viewing lines XVII-XVII of FIG. **14**.

FIG. **18** is a cross section of the expanded interbody fusion device as seen along the viewing lines XVIII-XVIII of FIG. **14**.

DESCRIPTION OF THE EMBODIMENTS

For the purposes of promoting and understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.

In accordance with one embodiment of the invention, an expandable interbody fusion device **10** includes a first superior endplate **12** and a second inferior endplate **14**, as shown in FIGS. **1-3**. The superior outer surface **12***a* and the inferior outer surface **14***a* of the endplates **12** and **14** each define engagement ribs **12***b* and **14***b* that are configured to engage or grip the vertebral endplates of opposed vertebral bodies in a spine. Preferably, the ribs **12***b* and **14***b*, as shown also in FIGS. **5-6** are configured to prevent expulsion of the device **10** under normal spinal loads. For instance, the ribs as shown may have a pyramidal configuration or they may include a saw tooth shape that is inclined toward the opening through which the device is inserted into the intradiscal space between opposing vertebral bodies.

The interbody fusion device **10** has a height across the superior and inferior endplates **12**, **14** in the unexpanded condition that is less than the normal anatomic height of a typical intradiscal space. The invention contemplates that a series of expansion members, such as interlocking wafers **100** as will be described, are introduced into the device **10** to distract the opposing vertebrae by separating the superior and inferior endplates **12**, **14** in situ. Insertion of the wafers **100** separates the endplates **12**, **14** to expand the height of the device within the intradiscal space and to ultimately restore the normal anatomic height of the disc space. Expansion devices of this type are shown and described in the '998 patent, the '688 patent and the '867 patent described hereinabove and incorporated herein by reference.

The present invention contemplates an improved interbody fusion device **10** that particularly includes openings and holes that define graft chambers for containment of materials that promote bone fusion through the device between opposing vertebral bodies. The inferior endplate **14** of the interbody fusion device **10** as shown in FIGS. **1-3** is elongate and comprises a pair of oppositely spaced apart sidewalls **16** and **18** extending along the longitudinal direction and projecting upwardly from outer surface **14***a*. A pair of spaced apart end walls **20** and **22** extend laterally across the device and project upwardly from the outer surface **14***a*. End wall **20** is disposed at the rear or proximal end of the device **10** and end wall **22** is disposed at the front or distal end of the device **10**. The side walls **16**, **18** together with rear end wall **20** and front end wall **22** form an open, upwardly facing full bounded cavity **24** as shown in FIGS. **3** and **4**.

The inferior plate **14** as shown in FIGS. **1** and **4** defines a wafer channel **26** through the rear end wall **20** and through which the wafers **100** which serve as expansion members are introduced. The inferior endplate **14** includes a pair of opposite ledges **28** that define an upper support surface on which each wafer **100** is supported as it introduced into the wafer channel **26**, as will be described. The inferior endplate **14** also defines an inserter channel **30** that is below and in communication with the wafer channel **26**. The ledges **28** define the bottom surface of the cavity **24**. The inserter channel **30** receives a wafer track (not shown) for introduction of the wafers **100** as described in the '688 patent incorporated herein by reference. More specifically the inserter channel **30** includes a number of severable posts **32** projecting upward therein that are configured to engage an insertion plate and a release plate in a manner as described in the '688 patent.

By continued reference to FIGS. **3-4**, it can be seen that each opposite side wall **16**, **18** of the inferior endplate **14** has on an interior surface **16***b* thereof a pair of ribs **34** projecting into the cavity **24**, the ribs **34** being spaced lengthwise on the interior of each side wall **16**, **18**. Each side wall **16**, **18** further defines upper surfaces **16***a* and **18***a* extending lengthwise thereon and generally parallel to each other. Rear end wall **20** defines a recess **20***a* extending therein at that the upper surface thereof and front end wall **22** defines a recess **22***a* extending therein at the upper surface thereof.

As shown particularly in FIGS. **4** and **6**, the inferior endplate **14** includes graft chambers defined by a pair of spaced openings **36** extending in alignment along the longitudinal direction. The openings **36** extend through the outer surface **14***a* of the inferior endplate **14**, through the support surfaces defined by ledges **28** and communicate with the cavity **24**. A web **38** extends between the pair of openings **36**, the web **38** supporting one of the posts **32** that is used to engage an insertion plate and a release plate as indicated hereinabove. One other post **32** is disposed between a first opening **36** and the rear end wall **20** and a further post **32** is disposed between the second opening **36** and the front end wall **22**, the three posts **32** and two openings **36** extending linearly along the longitudinal direction of the inferior endplate **14**. Each opening **36** includes therearound a countersink surface **36***a* as shown in FIG. **6** for receipt of bone graft to thereby increase the surface area of contact between such bone graft and the endplate of a vertebral body. At least one radiopaque marker **39** may be included on the inferior endplate **14**, such as adjacent the proximal end of side wall **16** and distal end of sidewall **18**, as shown in FIGS. **1-2** to assist in the visualization of the insertion of device **10** into the intradiscal space.

The superior endplate **12** as shown in FIGS. **1-3** and **10-11** is elongate and comprises a hub **40** having pair of side surfaces **42** and **44** extending longitudinally on each side of the hub **40** and a pair of end surfaces **46** and **48** extending respectively at the proximal end and the distal end of the superior endplate **12**. The hub **40** is sized and configured to fit within the cavity **24** in relatively close fit between the side walls **16** and **18** and the end walls **20** and **22** of the inferior endplate **14**. The lower surface **50** of the hub **40** (FIG. **11**) includes a shaped configuration defined by wafer mating features **52** that are substantially identical to the mating features on the lower surface of each wafer **100**, as will be described. Superior endplate **12** includes a flange **54** projecting outwardly and longitudinally from the hub **40** at the rear proximal end surface **46** and a flange **56** projecting outwardly and longitudinally from the hub **40** at the front distal end surface **48**. The hub **40** defines a groove **58** and **60** as shown in FIGS. **3** and **11** extending along each side **42** and **44** thereof that is configured to engage the ribs **34** of the inferior endplate **14**. This engagement temporarily holds the superior and inferior endplates together as the device **10** is introduced into the intradiscal space to be distracted.

As shown particularly in FIGS. **1-3** and **5**, the superior endplate **12** includes a graft chamber defined by a multi-contoured opening **62** extending through the upper surface **12***a* and the lower surface **50**. The opening **62** is considered multi-contoured since it has one configuration opening at the upper surface **12***a* and a different configuration opening at the lower surface **50**. In this particular arrangement, upper portion of opening **62** is a single, oval-shaped opening **62***a*. The lower portion of opening **62** comprises a pair of generally circular openings **62***b* separated by a cross member **64** disposed generally centrally and transversely across superior endplate **12** in the lateral direction. Openings **62***b* extend generally linearly along the longitudinal direction of superior endplate **12** and are disposed therethrough such that in assembly with inferior endplate **14** openings **62***b* are generally in alignment in the elongate direction with openings **36** through inferior endplate **14**. While the provision of cross member **64** may tend to reduce the area through which the bone graft may flow upon injection into the device **10**, it should be appreciated that the cross member **64** at the lower portion of superior endplate **12** provides strength to the superior endplate **12** while allowing greater bone graft area at the outer surface **12***a*. In addition, cross member **64** allows for a locking location for the uppermost wafer **100**, as will be described. It should also be appreciated that other multi-contoured shapes of openings may be used as alternatives to the illustrated and described multi-contoured opening **62**. Radiopaque markers **66** may be included on the outer surface **12***a* of superior endplate **12** as shown, for example in FIG. **5**.

Details of an interlocking wafer **100** are shown in FIGS. **7-9**. The wafer **100** is elongate and has an upper surface **102** and a lower surface **104**, both of which are generally planar so that the wafers can form a stable stack within the interbody fusion device **10**. The trailing proximal end **106** includes a downward-facing sloped surface **108** that corresponds angularly to an upward-facing surface **110** on the leading distal end **112** of the wafer **100**. The two sloped surfaces help displace an earlier inserted wafer **100** upon introduction of a new wafer. More specifically, when a first wafer is within the wafer channel **26**, resting on the ledges **28** (FIG. **11**), the downward-facing sloped surface **108** thereof is lifted upon contact with the upward-facing slope **110** of a newly inserted wafer. This allows the newly inserted wafer to ride along the ledges **28** until it is positioned fully underneath the previous wafer. The wafer **100** further includes notches or indentations **114** that are configured to receive the ribs **34** on the inner side walls **16**, **18** of the inferior plate **14** (see FIG. **11**) in a manner similar to the grooves **58** and **60** in the hub **40** of the superior endplate **12**.

The wafer **100** includes several features for interlocking engagement to the hub **40** and to adjacent wafers **100** in a complementary interlocking mating interface. One particular feature includes a series of locking elements defined by resiliently deflectable prongs **116** that project outwardly above the upper surface **102** of the wafer. In one arrangement, the prongs **116** are disposed along the wafer **100**, extending lengthwise in alignment and defining a plurality of resiliently deflectable locking surfaces therealong. The lower surface **104** of each wafer **100** as shown in FIGS. **8** and **11** also defines a T-slot configuration for mating with a T-bar configuration on the upper surface **102** of a successive wafer **100**. It should be appreciated that the respective T-bar and T-slot configurations may be formed on either the upper surface or the lower surface of a wafer **100** as desired. The structure and function of a wafer **100** and the prongs **116** are more fully described in the '867 patent, incorporated herein by reference. In the illustrated arrangement, there are three prongs **116** extending generally linearly along the elongate longitudinal direction. A pair of holes **118** extends through the upper surface **102** and the lower surface **104** of each wafer **100**. The holes **118** are provided to allow bone graft to flow through the wafers, the holes **118** being disposed along the longitudinal direction with at least one hole **118** being situated between each pair of prongs **116**. Of course, it is contemplated that fewer or greater numbers of prongs **116** and holes **118** may be provided in a wafer **100** within the scope of the present invention. For instance, the number of prongs **116** and holes **118** may be adjusted based on the length of the wafer **100**.

The superior and inferior endplates **12** and **14** are configured to be initially releasably engaged when the device **10** is unexpanded, as shown in FIGS. **1** and **2**. In this unexpanded condition, the device **10** is attached to a track assembly as described in the '867 patent. In this stage, the hub **40** is disposed within the cavity **24** of inferior endplate **14** with the ribs **34** on the interior surfaces of side walls **16**, **18** engaging the grooves **58** and **60** extending along each side of the hub **40**. The lower surface **50** of hub **40** is on or closely adjacent to the wafer support ledges **28** in facing relationship. This engagement temporarily holds the superior and inferior endplates together as the device **10** is introduced into the intradiscal space to be distracted. In this unexpanded condition the outer surface **12***a* of the superior endplate **12** is substantially flush with the upper surfaces **16***a* and **18***a* of the sidewalls **16** and **18**, with the flanges **54** and **56** residing in recesses **20***a* and **22***a* of the rear end wall **20** and the front end wall **22** of the inferior endplate **14**, as illustrated in FIGS. **1** and **2**. Such nesting of the superior endplate **12** within inferior endplate **14** allows for lower height of the unexpanded device **10**.

The manner in which the interbody fusion device **10** is expanded is illustrated in FIGS. **10-11**. When the first wafer **100** is introduced, the interlocking features on the upper surface **102** of the wafer **100** engage the mating features **52** on the lower surface **50** of superior endplate **12** lifting the superior endplate **12** upwardly within the cavity **24** between sidewalls **16**, **18** and breaking the initial releasable engagement. When the first inserted wafer **100** is introduced into the device **10** the holes **118** in the wafer **100** are located to be in alignment and communication with the openings **62***b* extending through the lower surface **50** of inferior endplate **12**. The locking elements **116** lockingly engage the lower surface **50**, one adjacent each of the distal and proximal ends of superior endplate **12** and the generally central locking element lockingly engaging the lower surface of cross member **64** extending between the openings **62***b*. This process continues with each successive wafer **100** inserted beneath a previously inserted wafer **100** until a complete stack is formed, as depicted in FIGS. **10-11**. As each subsequent wafer **100** is introduced, the locking elements **116** lockingly engage the mating features on the lower surfaces of each previously introduced wafer **100**, with the holes **118** of each wafer **100** being inserted such that they are in alignment and communication with the holes **118** of each previously introduced wafer **100**. The lowermost wafer **100** is supported on the support surfaces of ledges **28** with the holes **118** therethrough being in alignment and communication with the openings **36** extending through inferior endplate **14**. It should be noted that preferably all the wafers **100**, but at least the two lowermost wafers **100**, are contained within and constricted by the opposing side walls **16**, **18** and the rear and front end walls **20**, **22** so as to provide additional resistance against torsional movement of the spine. The manner in which the expanded interbody fusion device **10** is released from the wafer track assembly of the insertion instrument by the severing of posts **32** is fully described in the '867 patent.

Having described the interbody fusion device **10**, a suitable bone filler or bone graft to promote fusion between opposing vertebral bodies may be inserted into the expanded device **10** as well as into the intradiscal space adjacent to device **10**. With the instrument used to insert device **10** having been removed from the expanded device **10**, it can be appreciated that the wafer insertion channel **30** provides access into the expanded device **10**. A suitable graft insertion instrument may be used to inject bone graft under pressure into the expanded device **10**. Under an appropriate pressure, such bone graft will flow through the holes **118** extending through the wafers **100** and into the openings **36** through the inferior endplate **14** and into the multi-contoured opening **62** through the superior endplate **12**. The bone graft will also flow into the countersink surfaces **36***a* surrounding the openings **36** so as to further increase contact area between the bone graft and the endplate of the inferior vertebral body. Injection of the bone graft will continue until the graft is stress loaded against the endplates of the opposing vertebral bodies. In some instances, bone graft may be pre-loaded into an unexpanded device **10** prior to insertion of the device **10** into the intradiscal disc space. Suitable bone graft materials may include autograph bone, allograft bone, bone morphogenic protein (BMP) and xenograft and synthetic derived bone substitutes, as described for example, in the '998 patent. It should also be understood that a material with a bone fusion promoting substance, such as a sponge saturated with BMP, may be placed in the single opening **62***a* of the multi-contoured opening **62** and supported by the cross member **64**. This will allow the fusion promoting substance to be pre-loaded into device **10** and not be disrupted upon expansion of device **10** by insertion of wafers **100** as described herein.

It is contemplated that each of the components of the device **10**, namely the superior endplate **12**, inferior endplate **14** and the wafers **100** described herein, be formed of a biocompatible material that is sufficiently rigid to form a solid stack as the successive wafers are inserted into the device. Thus, in one specific embodiment, the components are formed of PEEK or a carbon-fiber reinforced PEEK, or similar polymeric material. Alternatively, the superior and inferior plates may be formed of a biological material, such as a bone graft material, or an osteoconductive or osteoinductive material.

In accordance with certain specific applications, the device **10** has particular utility as a lateral implant for insertion into the intradiscal space using a lateral approach as more fully described in PCT Application No. PCT/US2012/054055, entitled "Lateral Approach Expandable Spinal Implant and Method", filed on Sep. 7, 2012 and commonly assigned to the same assignee as the present invention, the disclosure of which is incorporated herein by reference in its entirety. As such, the overall length L of the device **10** as shown in FIGS. **5-6**, including the lengths of both the superior endplate **12** and the inferior endplate **14**, is about 37 mm. The width Ws of the superior endplate **12** is approximately 12.5 mm and the width Wi of the inferior endplate **14** is approximately 17.3 mm. The height of the unexpanded device **10** of FIGS. **1-2** with the superior endplate **12** fully nested within the inferior endplate **14** is approximately 8 mm. With the introduction of four wafers **100**, each of which has a thickness of approximately 1.0 mm, the height of device **10** may be expanded from an unexpanded height of approximately 8 mm to an expanded height of approximately 12 mm. Of course, the number of wafers may vary depending upon the particular surgery and the initial height may also be different. For example, device **10** may be formed to have an initial unexpanded height of 9 mm and with the addition of five wafers **100**, each having a thickness of 1 mm, the height of device **10** may be increased to 14 mm. As such, it should be appreciated that these dimensions are only illustrative and that the dimensions of the device **10** and the number of wafers **100** to be inserted and their thicknesses may vary depending upon the application.

The footprint of the outer surfaces of the superior and inferior endplates **12**, **14** that contacts the endplates of opposing vertebral bodies is determined by the area defined by the perimeter of such outer surfaces. Thus the footprint of outer surface **12***a* is L times Ws, as shown in FIG. **5**. In the particular example above with device **10** having a 37 mm length, the footprint is approximately 461 mm^2. The bone graft area that contacts the endplate of the superior vertebral body is defined by the area of the single opening **62***a*, which in this example is approximately 95 mm^2. The ratio of bone graft area to the footprint at outer surface **12***a* is therefore about 20.6%. The footprint of the outer surface **14***a* of the inferior endplate **14** that contacts the endplate of the inferior vertebral body is defined by the area, L times Wi, as shown in FIG. **6**. In this particular example, the footprint is approximately 639 mm^2. The bone graft area that contacts the endplate of the superior vertebral body is defined by the total area of the two openings together with the countersink areas **36***a*, which in this example is approximately 98 mm^2. The ratio of bone graft area to the footprint at outer surface **14***a* is therefore about 15.3%.

Turning now to FIGS. **12-18** a second embodiment of the invention is described. An expandable interbody fusion device **200** comprises a superior endplate **212**, an inferior endplate **214** and a plurality of interlocking wafers **300**. Components of interbody fusion device **200** are substantially the same both structurally and functionally as like components of interbody fusion device **10**, except for several differences. The first difference is that device **200** is of smaller size than device **10** and is particularly shorter in length. The device **200** thus has particular utility as a spinal implant inserted posteriorly or posteriolaterally either bilaterally or unilaterally depending upon the surgical indication and the surgeon's preference.

The second difference of device **200** over device **10** is that the superior endplate **212** is not fully nested within the sidewalls **216**, **218** and the front end wall **220** and the rear end wall **222** of device **200**. Each side wall **216**, **218** defines upper surfaces **216***a* and **218***a* extending lengthwise thereon. Rear end wall **220** defines a recess **220***a* extending therein at that the upper surface thereof and front end wall **222** defines an upper surface **222***a* coplanar with upper surfaces **216***a* and **218***a*. Superior endplate **212** includes a flange **254** projecting outwardly and longitudinally from the hub **240** at the rear proximal end surface **246** and a flange **256** projecting outwardly and longitudinally from the hub **240** at the front distal end surface **248** at the front distal end surface **248**. Flanges **257** and **259** project outwardly and laterally from the hub **240** from hub side surfaces **242** and **244**, respectively. In the unexpanded condition, the flanges **256**, **257** and **259** rest on top of respective upper surfaces **222***a*, **216***a* and **218***a* with a flange **254** residing in recess **220***a*. While not fully nested in a manner as provided with device **10**, the added expanse of the flanges **256**, **257** and **259** provides for a larger footprint than the fully nested structure.

A third difference of device **200** over device **10** is that device **200** has multi-contoured openings at both the upper surface **212***a* and **214***a*, as shown in FIGS. **15** and **16**. The superior endplate **212** has an opening **262** therethrough, the upper portion of opening **262** being a single, oval-shaped opening **262***a*. The lower portion of opening **262** comprises a pair of generally rectangular openings **262***b* separated by a cross member **264** disposed generally centrally and laterally across superior endplate **212**. Openings **262***b* extend generally linearly along the longitudinal direction of superior endplate **12**. The inferior endplate **214** has an opening **236** therethrough, the lower portion of opening **236** being a single, oval-shaped opening **236***a*. The upper portion of opening **236** comprises a pair of generally rectangular openings **236***b* separated by a cross member **238** disposed generally centrally and laterally across inferior endplate **214**.

Openings **236***b* extend generally linearly along the longitudinal direction of superior endplate **12** and are disposed therethrough such that in assembly with superior endplate **212** openings **236***b* are generally in alignment in the elongate direction with openings **262***b* through superior endplate **212**. It should be appreciated that the area of bone graft contact with the endplates of opposing vertebral bodies may be maximized by the use of the multi-contoured openings **236** and **262** each of which has a substantially large single oval-shaped opening **236***a* and **262***a*, respectively, while maintaining strength of the endplates **212**, **214** due to the cross members **238** and **264**.

A fourth difference of device **200** over device **10** is that the ribs **212***b* and **214***b* are configured to include a saw tooth shape rather than the pyramidal configuration of the ribs **12***b* and **14***b* of the device **10**.

The expansion members defined by interlocking wafers **300** are substantially similar to wafers **100** except for size and are inserted in a similar manner such that once inserted the holes **318** are aligned and in communication with openings **236***b* through the inferior endplate **214** and with openings **262***b* through the superior endplate **212**.

In an example of the second embodiment, the overall length L of the device **200** is about 25 mm and the overall width is approximately 12 mm. The height of the unexpanded device **10** of FIGS. **12-13** is approximately 7 mm. With the introduction of each wafer **300** having a thickness of approximately 1.0 mm, the height of device **200** may be expanded in 1 mm increments. As such, the insertion of one wafer **300** would increase the height of device **200** to 8 mm while the addition of three wafers **300** would increase the height to 10 mm. As with device **10**, it is preferable that all the wafers **300**, but at least the two lowermost wafers **300** where more than a single wafer is inserted, be contained within and constricted by the opposing side walls **216**, **218** and the rear and front end walls **220**, **222** so as to provide additional resistance against torsional movement of the spine. It should be appreciated that with this embodiment other unexpanded starting heights and lengths of device **200** may be contemplated as well as different number of wafers **300** and wafer thicknesses, depending upon the particular application. For example, a device having an overall length of approximately 29 mm and a width of approximately 12 mm may have an unexpanded height of about 9 mm with three wafers **300** inserted to thereby increase the height to about 12 mm.

In the particular example above with device **200** having a 25 mm length, the footprint of outer surface **212***a* of superior endplate **212** is approximately 283 mm^2. The bone graft area that contacts the endplate of the superior vertebral body is defined by the area of the single opening **262***a*, which in this example is approximately 78 mm^2. The ratio of bone graft area to the footprint at outer surface **212***a* is therefore about 27.6%. The footprint of the outer surface **214***a* of the inferior endplate **214** that contacts the endplate of the inferior vertebral body in this particular example is approximately 305 mm^2. The bone graft area that contacts the endplate of the inferior vertebral body is defined by the area of the single opening **236***a*, which in this example is approximately 78 mm^2. The ratio of bone graft area to the footprint at outer surface **214***a* is therefore about 25.6%. Accordingly, the ratio of bone graft area to the footprint at the outer surfaces of the expandable interbody fusion devices in the examples ranges from about 15 to 28%.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. It is understood that only the preferred embodiments have been presented and that all changes, modifications and further applications that come within the spirit of the invention are desired to be protected. For instance, the superior and inferior endplates of the expandable interbody fusion device may each have a single opening extending therethrough in communication and alignment with at least one expansion members defined by an interlocking wafer. Such wafer would have at least two locking elements thereon, one locking element being located on each side of the hole through such wafer, such that a locking engagement would be provided at each of the proximal and distal ends of the device. Also, while the illustrated embodiments have been directed to interbody fusion of the spine, the expandable devices and wafers disclosed herein may be used in other applications that require distraction of tissue surfaces. Modifications in size may be necessary depending upon the body space being distracted.

What is claimed is:

1. In an improvement of an expandable interbody fusion device for implantation into an intradiscal space between two opposing vertebral bodies of a spine, said device comprising:

a first elongate endplate having a proximal end and a distal end and a longitudinal axis extending between the proximal and distal ends of the first elongate endplate and an outer surface defining a first perimeter configured to contact one of said vertebral bodies and a hub having an inner mating surface opposite to said outer surface of the first elongate endplate, said hub being defined by opposing sides surfaces and opposing end surfaces depending downward from said outer surface of the first elongate endplate,

a second elongate endplate having a proximal end and a distal end and a longitudinal axis extending between the proximal and distal ends of the first elongate endplate and an outer surface defining a second perimeter configured to contact the other of said vertebral bodies and a cavity having an inner support surface opposite to said outer surface of the second elongate endplate, said cavity being defined by opposing side walls and opposing end walls projecting upward from said inner support surface of the second endplate and terminating in respective top surfaces, said first elongate endplate and said second elongate endplate being aligned relative to each other in an elongate direction along the longitudinal axes, and wherein the opposing side and end surfaces defining the hub are configured to slide within said cavity along an expanding direction traversing the elongate direction from a retracted configuration wherein said hub is housed within said cavity of the second elongate endplate to an expanded configuration wherein the outer surface of the first elongate endplate moves apart from the opposing side walls of the second elongate endplate, thereby increasing a height of the device in the expanding direction, and

an expandable structure comprising at least one elongate expansion member having a central axis extending between proximal and distal ends and opposing upper and lower surfaces, said at least one expansion member being sized to be received into said device through a through channel in one of the opposing end walls of the second elongate endplate and supported on said inner support surface between said first endplate and said second endplate when in the retracted configuration, and upon receipt therein moves said first endplate and said second endplate relatively apart from one another, wherein said at least one elongate expansion member is movable between said first elongate endplate and said second elongate endplate in the elongate direction to separate said first elongate endplate and said second elongate endplate and effect expansion of said device from the retracted configuration to the expanded configuration, the improvement wherein:

said first endplate has a multi-contoured opening extending therethough and fully disposed within said first perimeter, said multi-contoured opening having a single opening through the outer surface of said first endplate and at least two openings through an inner mating surface of said first elongate endplate and communicating with said single opening, said two openings at the inner mating surface of said first endplate being spaced from one another in the elongate direction by a cross member extending transversely across the first elongate endplate at the inner mating surface thereof, said first elongate endplate defining at the inner mating surface thereof a shaped configuration with mating features for interlocking engagement with said at least one expansion member of the expandable structure at said cross member and one of the proximal end and the distal end of said first elongate endplate during movement of said at least one expansion member of said expandable structure in the elongate direction between the first and second elongate endplates in the retracted configuration; and

said at least one expansion member has at least two locking elements projecting from said upper surface of said at least one expansion member, said at least two locking elements extending along said central axis and at least two through holes located along said central axis and spaced a distance from one another in the elongate direction, wherein one of said at least two locking elements is disposed adjacent to one of the proximal and the distal ends of the at least one expansion member and a second one of the at least two locking element is disposed between said at least two through holes such that upon receipt of said at least one elongate expansion member into said device between the first and the second elongate endplates in the retracted configuration, said at least two locking elements interlock with the mating features of said inner mating surface at said cross member and at one of the proximal and the distal ends of said first elongate endplate and said at least two through holes are aligned with said two openings through the inner mating surface of said first elongate endplate and the first and the second elongate endplates move apart from one another in the expanded configuration.

2. The improvement of claim **1**, wherein said lower inner mating surface of said first endplate and said upper inner support surface of said second endplate face each other in the retracted and expanded configurations, said second endplate having at least one opening extending through said outer surface and through said upper inner support surface.

3. The improvement of claim **2**, wherein said at least two locking elements comprises a third locking element disposed adjacent the other of the proximal and distal ends of said at least one expansion member.

4. The improvement of claim **3**, wherein said third locking element is configured to interlock with a third mating feature at the other of the proximal and distal ends of the inner mating surface of said first endplate.

5. The improvement of claim **4**, wherein said said at least one opening of said second endplate comprises two openings extending through said outer surface and said inner support surface along the elongate direction, said two openings of said second elongate endplate being located such that upon receipt of said elongate expansion member into said device said two openings of said second elongate endplate communicate with said two holes through said expansion member.

6. The improvement of claim **5**, wherein each of said locking elements comprises a resiliently deflectable locking surface.

7. The improvement of claim **2**, wherein said expansion member is defined by an elongate wafer having side edges between said opposing upper and lower surfaces.

8. The improvement of claim **7**, wherein said device comprises at least one further wafer received between said wafer and said inner support surface of said second endplate, said further wafer defining a resilient interlocking interface with said wafer, said wafer and said further wafer being contained within the sidewalls of said second endplate.

9. The improvement of claim **2**, wherein said at least one opening extending through said outer surface and said inner support surface of said second endplate is a multi-contoured opening.

10. The improvement of claim **9**, wherein said multi-contoured opening through said second endplate has a single opening through the outer surface of said second endplate and at least two openings through the inner support surface of said second endplate communicating with said single opening.

11. The improvement of claim **10**, wherein said two openings at said inner support surface extend along the elongate direction.

12. The improvement of claim **11**, wherein said two openings at the inner support surface of said second endplate are spaced by a cross member extending transversely across the second endplate at the inner support surface thereof.

13. The improvement of claim **12**, wherein the perimeter of the outer surfaces of each of said first endplate and said second endplate defines a respective footprint, and wherein each of the openings of said first endplate and said second endplate defines a bone graft area for contacting opposing vertebral bodies.

14. The improvement of claim **13**, wherein the ratio of the bone graft area to the footprint of at least one of said first endplate and said second endplate ranges from 15 to 28%.

* * * * *